REMARKS

The pending Office Action addresses claims 1-15 and 17-20, rejecting claims 1, 3-5, 7, 8, 12, 14, 15, 17, and 20, and objecting to claims 2, 6, 9-11, 13, 18, and 19.

Claim Amendments

In order to expedite prosecution, claim 1 is amended to include the features of allowable claim 6, and claim 6 is canceled. Applicant reserves the right to pursue the subject matter of original claim 1 in a continuation application. Claim 14 is amended to recite that an infusion pump is "adapted to be implanted" in a subject. Claim 20 is amended to recited that the biochemical parameters are "related to the central nervous system of a subject," a feature similar to the one recited in allowable claim 6. No new matter is added.

Claim Rejections under 35 U.S.C. § 102

Claims 1, 3, 5, 7, 8, 12, 14, 15, 17, and 20 are rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,558,351 of Steil et al.

As stated above, independent claim 1 is amended to include the features of allowable claim 6. Thus, claim 1, and claims 3, 5, 7, 8, and 12 which depend therefrom, are in condition for allowance.

Independent claim 14 recites a method of drug treatment. The method comprises providing an infusion pump adapted to be implanted at a site in a subject. The pump includes a housing having a chamber for containing one or more drugs and being operable to deliver the drug from the infusion pump. The method further includes providing a delivery pathway from the infusion pump to a target tissue site within the subject, and providing a sensor configured for implantation at a sensing location in the subject. The sensor is adapted to detect a biochemical parameter or event at the sensing location and to produce an output signal indicative thereof. A control unit implantable at a site in a subject is provided. The control unit is able to receive the output signal from the sensor and is in communication with the infusion pump. The control unit controls drug delivery from the infusion pump, responding to data provided by the output signal in a closed loop feedback cycle to

regulate delivery of the drug from the infusion pump so as to release the drug at the target site to maintain the sensed biochemical parameter or event within a predetermined range. The control unit includes a processor and a memory, and the processor compiles and stores a database of sensed data and response data, and responds to the compiled and stored data to create and adjust a treatment model.

Steil does not teach all the features of claim 14. Specifically, Steil does not disclose an infusion pump adapted to be implanted at a site in a subject. Instead, Steil teaches an infusion device 34 and infusion set 38 worn externally on a subject's body, the two devices being connected by an infusion tube 36 (see FIG. 2 of Steil). None of these insulin-delivery components is implanted within the subject's body. The only component inserted into the subject's skin is a cannula 56, which delivers the insulin to the tissue. This cannula is not an infusion pump as recited in claim 14, but rather could be better compared to the delivery pathway from the infusion pump to a target tissue site within the subject as recited in the claim. Thus, Steil does not teach an infusion pump *adapted to be implanted* in the subject.

Accordingly, Steil does not teach all the features of claim 14, and claim 14 and claims 15 and 17, which depend therefrom, distinguish over Steil.

Independent claim 20 recites a method for delivering an effective amount of a drug to a subject. The method comprises sensing one or more biochemical parameters related to the central nervous system of a subject in response to the delivery of a drug to produce sensed signals. A dose-response database is created from the sensed signals, and appropriate pump control parameters are modeled for maintaining desired conditions based on the dose-response database. A drug is delivered to a subject from a drug delivering pump operated under the appropriate pump control parameters. The step of sensing one or more biochemical parameters is repeated to modify the dose-response database and to model appropriate pump control parameters.

Steil does not teach all of the features of claim 20. Specifically, Steil does not teach sensing biochemical parameters related to the central nervous system of a subject. Instead, the device in Steil is only utilized in the delivery of insulin, and makes no mention of use in the central nervous

system of a subject. Accordingly, Steil does not teach all the features of claim 20, and thus claim 20 distinguishes over Steil.

Claim Rejections under 35 U.S.C. § 103

Claim 4 is rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Steil. As explained above, independent claim 1 is amended to include the features of allowable claim 6. Claim 4, which depends from claim 1, therefore distinguishes over Steil at least because it depends from an allowable base claim.

Conclusion

In view of the above amendment, Applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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